REMARKS

The examiner considers the application to contain inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1 and requires election of a single invention or group from Groups 1-102. The examiner takes the position that the first claimed invention fails to recite a special technical feature which defines a contribution over the prior art, citing EP218531 for its disclosure of an immunogenic peptide derived from IL-1β which is identical to instant SEQ ID NO:1.

Applicant elects with traverse Group 6, claims 1-11 and 14, drawn to the fragment of hTNF alpha of SEQ ID NO:6. Traversal is based on the fact that generic claim 1 as amended recites a special technical feature shared by the presently claimed peptides which define a contribution over the prior art. Amended claim 1 now recites a proviso that excludes instant SEQ ID NO:1 from the claims. As stated in MPEP 2173.01:

> A fundamental principle contained in **35 U.S.C. 112**, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as **>any special meaning assigned to a term is clearly set forth in the specification. See MPEP § **2111.01.**< Applicant may use functional language, alternative expressions, negative limitations, or any

> style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. (emphasis added)

MPEP 2173.05(i) on Negative Limitations states:

> The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of **35 U.S.C. 112**, second paragraph. Some older cases were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention. Thus, the court observed that the limitation "R is an alkenyl radical other than 2-butenyl and 2,4-pentadienyl" was a negative limitation that rendered the claim indefinite because it was an attempt to claim the invention by excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent. *In re Schechter*, 205 F.2d 185, 98 USPQ 144 (CCPA 1953).
>
> A claim which recited the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite. *In re Wakefield*, 422 F.2d 897, 899, 904, 164 USPQ 636, 638, 641 (CCPA 1970). In addition, the court found that the negative limitation "incapable of forming a dye with said oxidized developing agent"

> was definite because the boundaries of the patent protection sought were clear. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).
>
> Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). (emphasis added)

The decision in *In re Johnson* 194 USPQ 196 (CCPA 1977), which is what is currently accepted by the courts and the USPTO, states:

> The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.
>
> The board indicated that "it is manifestly immaterial" *why* appellants limited their claims. Though it is true that insufficiency under §112 could not be cured by citing the causes for such insufficiency, it is not true that the factual context out of which the question

> under §112 arises is immaterial. Quite the contrary. Here, as we hold on the facts of this case, the "written description" in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter."

In short, the positive recitation in the present specification of a peptide of SEQ ID NO:1 indeed provides adequate written description to excise what applicants are not entitled to from their claimed invention by the use of negative limitations. Such negative limitations, which have basis in the original disclosure only as positive recitations, are permitted and do not constitute new matter.

Active anti-cytokine immunization is an active immunotherapy which has been disclosed in WO92/22577 (corresponding to US Patent 6,093,405), which patients are immunized with "whole" cytokine protein as immunogen. This approach however may present the following risks:

1. It may generate antibodies which enhance the effect of the cytokine instead of neutralizing it.

2. An immune response against non relevant epitopes may be generated; and

3. It may trigger an autoimmune reaction against T epitopes present in the cytokine

The peptides and methods of using them according to the present invention improves the efficiency of this anti-cytokine immunization. By using cytokine peptides derived from the cytokine-receptor interaction zones of cytokines, the three risks described above are avoided. The single general concept of the present invention is a peptide and use thereof to improve the efficiency of cytokine immunization through a vaccine which contains at least one immunogenic compound comprising a cytokine peptide derived from the cytokine-receptor interaction zones. This is the first time that cytokine peptides derived from the cytokine-receptor interaction zones are contemplated for use in a vaccine for anti-cytokine immunization, with cytokine peptides derived from the cytokine-receptor interaction zones being defined by peptides of a size between 5 and 40 amino acids, originating from a cytokine, wherein at least one of its amino acids comprises at least one of its atoms separated by a distance d of less than 5 Angströms from an atom of the receptor for said cytokine when said cytokine is bound to the receptor, the spacing d being evaluated on the basis of structural data. This is the special technical feature shared by all the

embodiments of the present invention that defines a contribution over the prior art.

Reconsideration and withdrawal of the restriction requirement are therefore respectfully requested.

Applicant has elected product claims. It is understood that even if the requirement is maintained, once an elected product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claims will be rejoined in accordance with the provisions of MPEP 821.04.

Support for the amendment to claims 1 and 2 is implicit from the specification and is further supported by Figures 1 and 2 and the description of Figures 1 and 2 at page 13 of the specification.

It is noted that the Drawings (Figures 1 and 2) from publication WO 03/084179 of PCT International application PCT/FR03/01120 (from which the instant application is a 371 national stage application) forwarded by the International Bureau was received by the USPTO and made of record in the present application, as can be seen on PAIR. However, no acknowledgement of such a drawing is made by the PTO. Attached hereto is a formal sheet of Drawing (Figures 1 and 2) for entry into the file. Entry and acknowledgement are respectfully requested.

Favorable consideration and allowance are hereby respectfully solicited.

Respectfully submitted,

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